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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,106	10/12/2001	Neal A. Hammond	461	1724

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Robert Charles Hill
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EXAMINER

HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 11/21/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,106

Applicant(s)

HAMMOND, NEAL A.

Examiner

Keith Hendricks

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of an alpha-amylase enzyme (see pages 4-5 of the specification), does not reasonably provide enablement for the use of any random “enzyme”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A number of factors must be considered in assessing the enablement of an invention, including the following: the breadth of the claims, the amount of experimentation necessary, the guidance provided in the specification, working examples provided, predictability, and the state of the art. See *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988).

The instant claims call for the addition of “an enzyme”, presumably “to obtain a hydrolysis of rice flour”. This would require, at the minimum, a hydrolase enzyme, to which the claims are not even limited, and to which the specification does not provide such support. The specification provides for the use of a single type of enzyme, namely alpha-amylase. The working examples utilize this enzyme. The specific activity of the alpha-amylase appears to be critical to the process, and to the properties of the end product. The addition of any other enzymatic activity, in its place, is not contemplated in such terms that one skilled in the art would be able to make and/or use the invention in an effective manner, and expect similar positive functional results. The amount of experimentation required to obtain, utilize, screen and determine the results from any other type of enzyme, of which there are thousands (as of the 1992 edition of *Enzyme Nomenclature*, 3450 entries were listed), would be enormous and undue. No reasonable expectation of success is provided with other enzyme types, nor is there any guidance as to the protocol effective with any other type of enzyme.

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ii) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “rice flour ingredient” is indefinite. It is unclear if this is equivalent to “rice flour”, or if this intended to be some component of rice flour (i.e. an “ingredient”). Further, if it is to mean “rice flour”, *per se*, then it is unclear in what larger product, the rice flour is an “ingredient”. It is suggested that the term “ingredient” be deleted from the phrase “rice flour ingredient”, in the claims.

Claims 1-5 and 7-14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are the addition of water or a rice syrup, in order to form a slurry to be extruded. The simple combination of flour and an enzyme would not produce a slurry, and thus extrusion of such a powdery composition would be difficult, if not impossible. Note that, in claim 7, the “blending of a sweetener”, for example, a granulated sugar, does not necessarily solve the issue.

Claims 15-16 and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: water or a rice syrup, in order to form a slurry to be extruded. The simple combination of flour and an enzyme would not produce a slurry, and thus extrusion of such a powdery composition would be difficult, if not impossible. In such a product “system” set of claims, if the “means for extruding a slurry” are given weight by this, their only description of the claim element, then all other essential claim elements must be present as well, in order for the claimed “system” to function.

The phrase “extruding a slurry” is indefinite, as it is unclear if this is the starting product to be extruded, or if this is the extruded end product. The act of “extruding a product” usually refers to the end product after extrusion. However, it is noted that, since the independent claims state that “a product is produced with a water content of 5%-25% by weight”, this would not normally be considered a slurry, and thus it is assumed that the former case is accurate. The claims should be amended to clarify such. See claim 6, which states that the slurry exists prior to the extrusion step. However, currently, claim 6 potentially conflicts with claim 1.

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Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The phrase “to obtain a hydrolysis of rice flour”, in claims 1 and 15, is indefinite. The role of the extruder and/or the enzyme, is unclear. It is unclear if the enzyme is to perform the hydrolysis, or if the extrusion process performs this task. If not the enzyme, then the role and necessity of the enzyme is unclear (see also the rejection under 35 U.S.C. 112, first paragraph, above). Further, it is unclear as to how the hydrolysis is performed, if the enzyme is not an active hydrolase (for example, the alpha-amylase disclosed). However, reference to claim 5, for example, implies that the extrusion process itself performs the hydrolysis, independent of the enzyme. Thus, claim 5 is also indefinite, as it is unclear as to how the rice flour ingredient is hydrolyzed by the extrusion process.

The phrase “to obtain a hydrolysis of rice flour” is indefinite and confusing as it exists in the claims. The phrase “to obtain a”, usually leads to a product obtained. The term “hydrolysis” is a process. Thus, the phrase “to obtain a hydrolysis”, is indefinite. Contrast this with the phrases “to effect a hydrolysis”, and “to obtain a hydrolyzed rice flour”.

Claim 3 provides for the “use” of the product, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. It is suggested that the phrase “adding... to”, be utilized, instead of “using...in”.

Claim 10 is also indefinite for the term “use”.

Claims 4 and 16 are indefinite for the following reasons:

- The term "short-time" is a relative term which renders the claim indefinite. The term "short" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
- The phrase “said rice flour” lacks a clear antecedent basis. Contrast this with the phrase “rice flour ingredient”, as used in claim 1, as addressed above.
- The phrase “conversion of said rice flour” is indefinite, as it is unclear into what new product the rice flour is “converted.”

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- The phrase “in the presence of said enzyme”, does not convey the purpose of the enzyme, nor the active method step performed by the claim.

Claim 5 is indefinite for the recitation of the phrase “sustain significant microbiological growth”.

- The term “sustain” is indefinite, as the claims and specification do not set forth a period of time over which this would be considered to apply.
- The term “significant” is indefinite, as the amount is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 6-7 and 16-17 are indefinite for the use of the phrase “said rice flour” (or “the rice flour”). As in claim 4, this lacks a clear antecedent basis. Contrast this with the phrase “rice flour ingredient”, as used in claim 1, addressed above.

Claim 6 is indefinite for the recitation of the phrase “providing for an enzymatic reaction”. The method steps to be carried out by one skilled in the art, are unclear, due to the phrase “providing for.”

Claim 8 is indefinite for the recitation of the phrase “the step of extruding is such that said product appears like shortening.” Initially, the conditions of extrusion are not provided, such that one skilled in the art would be able to make the invention, where “said product appears like shortening.” Secondly, the phrase “appears like shortening” is indefinite. This phrase may be interpreted as “shortening-like”; however, the properties of shortening being compared, such that one skilled in the art would recognize that the product “appears like shortening”, are not set forth. Further, the phrase “like” is indefinite, as it is unclear if this is a phrase imparting exactness, or one implying a similarity. If the latter, the degree of similarity is not set forth, and thus is a relative phrase where the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term “flours”, in claim 8, lacks a clear antecedent basis, as only a single “rice flour ingredient” had been stated previously.

The following phrases are indefinite, as they are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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- “substantially less” – claim 8.
- “bland, neutral taste” – claim 11.
- “adjust” – claim 12. It is unclear if this is an alteration of the pH to a more acidic or more basic level.
- “substantially comprises” – claims 21-22. It is unclear as to how an enzyme may comprise another enzyme (i.e. the amylase). Further, it is unclear as to what elements are, or are not, included by the term “substantially comprises”.

The phrase “can act”, in claim 9, is indefinite. It is unclear as to how one skilled in the art is to determine if a protein “can act” as an emulsifier, or any other type of food activity component. It is unclear under what conditions the proteins may or may not be considered to possess emulsifying properties. See also claim 20.

Claim 12 is indefinite, as it is unclear as to how the step of a second extrusion would serve to inactivate the enzymes and “adjust the pH” of the product, yet presumably, the initial extrusion would not provide this effect.

** It is suggested that claim 15 be amended to recite the following passages:

- “a slurry comprising water,
rice flour,
and an enzyme...” (it is further suggested that the specific enzyme, alpha amylase, be recited),
- “an extrusion means for extruding a slurry, wherein said slurry comprises said rice flour...”.

Prior Art Rejections and Considerations

NOTE: Claims 15-22 are directed to a “system”, comprising a rice flour ingredient, an enzyme, and a “means for extruding a slurry”. For purposes of examination herein, this “system” is considered to be a product claim (composition of matter), not an apparatus claim. An apparatus claim covers what a device *is*, not what a device *does*. See MPEP 2114.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 8-11, 15-16 and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Minami et al.

Minami et al. disclose a “method of manufacturing quick-soluble gelatinized powdered grain.” The method comprises adding an aqueous solution of a protease, also containing an amylase, to powdered rice, forming a paste, and forming strips from the paste. Example II discloses the process wherein the mixture is “extruded by an extruding machine”. At col. 2, lines 14-19, the reference states that “the formation of a thin strip is substantially the most efficient means to secure uniform dehydration in a short time.”

Thus, the claimed invention is anticipated by the reference. While the texture of the final product is not as fully characterized as applicants’ invention (for example, instant claims 5, 8, 11), it does indicate the same starting products, the same extrusion means, and that the final product is gelatinized with “uniform dehydration.” Thus, it would be expected that the disclosed process would be anticipated by the referenced process, absent any clear and convincing evidence and/or arguments to the contrary. The natural progression of the method would then also be expected to produce “proteins that can act as emulsifiers” (claims 9, 20). Regarding the ‘system’ claims 15-22, it is noted that the method steps provided in the dependent claims 18-19 are not given patentable weight, in that they do not change the claimed product itself. Finally, the reference discloses various sources for the amylase and protease enzymes, at col. 1. These sources naturally produce alpha-amylases (claim 22), which would thus be expected to be the amylase included in the disclosed preparation.

Claims 1-4, 8-9, 11, 15-16 and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Reddy et al.

Reddy et al. disclose the production of a two-part media system as an oxygen supplier in the form of extruded pellets. Rice flour (Tables 1, 3, 4; col. 8-line 66; example 12) is blended with enzymes, including amylase (top col. 13), and is processed by an extruder to form pellets. Regarding instant claims

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2-3, the 'use', or addition, of the product in feedstuffs and 'a final food product', is disclosed at example 4 and example 8. While the texture of the final product is not as fully characterized as applicants' invention (for example, instant claims 8, 11), it does indicate the same starting products, the same extrusion means, and that the final product is gelatinized. Thus, it would be expected that the disclosed process would be anticipated by the referenced process, absent any clear and convincing evidence and/or arguments to the contrary. The natural progression of the method would then also be expected to produce "proteins that can act as emulsifiers" (claims 9, 20). Regarding the 'system' claims 15-21, it is noted that the method steps provided in the dependent claims 18-19 are not given patentable weight, in that they do not change the claimed product itself.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


KEITH HENDRICKS
PRIMARY EXAMINER